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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a requ st for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

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INVENTOR(S)		
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☐ *Additional inventors are being named on the ____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

CARDIAC VALVE ANNULUS REDUCTION SYSTEM

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 20 ☐ CD(s), Number

☒ Drawing(s) *Number of Sheets* 10 ☐ Other (specify)

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☐ Applicant claims small entity status. See 37 CFR 1.27.

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: ____.

Respectfully submitted,

SIGNATURE [signature] Date 11/12/03

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TELEPHONE 847 905-7111 Docket Number: P1905 PRO (2650/194)

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This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

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TITLE: CARDIAC VALVE ANNULUS REDUCTION SYSTEM

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CARDIAC VALVE ANNULUS REDUCTION SYSTEM

TECHNICAL FIELD

[0001] The technical field of this disclosure is medical devices, particularly, a cardiac valve annulus reduction system and method of using the same.

BACKGROUND OF THE INVENTION

[0002] Heart valves, such as the mitral valve, tricuspid, aortic and pulmonic valves, are sometimes damaged by disease or by aging, which can cause problems with the proper function of the valve. Heart valve problems generally take one of two forms: stenosis, in which a valve does not open completely or the opening is too small, resulting in restricted blood flow; or insufficiency, in which blood leaks backward across the valve that should be closed. Valve replacement may be required in severe cases to restore cardiac function. In common practice, repair or replacement requires open-heart surgery with its attendant risks, expense, and extended recovery time. Open-heart surgery also requires cardiopulmonary bypass with risk of thrombosis, stroke, and infarction.

[0003] In various types of cardiac disease, mitral valve insufficiency may result. Any one or more of the mitral valve structures, i.e., the anterior and posterior leaflets, the chordae, the papillary muscles or the annulus may be compromised by damage from disease or injury, causing the mitral valve insufficiency. Typically, in cases where there is mitral valve insufficiency, there is some degree of annular dilatation resulting in mitral valve regurgitation. Mitral valve regurgitation occurs as the result of the leaflets being moved back from each other by the dilated annulus. Thus, without correction, the mitral valve insufficiency may lead to disease progression and/or further enlargement and

worsening of the insufficiency. In some instances, correction of the regurgitation may not require repair of the valve leaflets themselves, but simply a reduction in the size of the annulus.

[0004] A variety of techniques have been attempted to reduce the diameter of the mitral annulus and eliminate or reduce valvular regurgitation in patients with incompetent valves. Current surgery to correct mitral regurgitation in humans includes a number of mitral valve replacement and repair techniques.

[0005] Valve replacement can be performed through open-heart surgery, open chest surgery, or percutaneously. The native valve is removed and replaced with a prosthetic valve, or a prosthetic valve is placed over the native valve. The valve replacement may be a mechanical or biological valve prosthesis. The open chest and percutaneous procedures avoid opening the heart and cardiopulmonary bypass. However, the valve replacement may result in a number of complications including a risk of endocarditis. Additionally, mechanical valve replacement requires subsequent anticoagulation treatment to prevent thromboembolisms.

[0006] As an alternative to valve replacement, various valve repair techniques have been used including quadrangular segmental resection of a diseased posterior leaflet; transposition of posterior leaflet chordae to the anterior leaflet; valvuloplasty with plication and direct suturing of the native valve; substitution, reattachment or shortening of chordae tendinae; and annuloplasty in which the effective size of the valve annulus is contracted by attaching a prosthetic annuloplasty ring to the endocardial surface of the heart around the valve annulus. The annuloplasty techniques may be used in conjunction with other repair techniques. Typically such rings are sutured along the posterior mitral leaflet adjacent to the mitral annulus in the left atrium. The rings either partially or completely encircle the valve, and may be rigid or flexible/non-elastic. All of these procedures require cardiopulmonary bypass, though some less and minimally invasive techniques for valve repair and replacement are being developed.

[0007] Although mitral valve repair and replacement can successfully treat many patients with mitral valve insufficiency, techniques currently in use are attended by significant morbity and mortality. Most valve repair and replacement procedures require a thoractomy, to gain access into the patient's thoracic cavity. Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system and arrest of cardiac function. Open chest techniques with large sternum openings are typically used. Those patients undergoing such techniques often have scarring retraction, tears or fusion of valve leaflets as well as disorders of the subvalvular apparatus.

[0008] Recently other surgical procedures have been provided to reduce the mitral annulus using a less invasive surgical technique. According to this method, a prosthesis is transvenously advanced into the coronary sinus and the prosthesis is deployed within the coronary sinus to reduce the diameter of the mitral annulus. This may be accomplished in an open procedure or by percutaneously accessing the venous system by one of the internal jugular subclavian or femoral veins. The prosthesis is tightened down within the coronary sinus, located adjacent the mitral annulus, to reduce the mitral annulus.

[0009] While the coronary sinus implant provides a less invasive treatment alternative, the placement of the prosthesis within the coronary sinus may be problematic for a number of reasons. Sometimes the coronary sinus is not accessible. The coronary sinus on a particular individual may not wrap around the heart far enough to allow enough encircling of the mitral valve. Also, leaving a device in the coronary sinus may result in formation and breaking off of thrombus that may pass into the right atrium, right ventricle and ultimately the lungs causing a pulmonary embolism. Another disadvantage is that the coronary sinus is typically used for placement of a pacing lead, which may be precluded with the placement of the prosthesis in the coronary sinus.

[00010] It would be desirable, therefore, to provide a method and device for reducing cardiac valve regurgitation that would overcome these and other disadvantages.

SUMMARY OF THE INVENTION

[00011] One aspect of the present invention provides a cardiac valve annulus reduction system to provide catheter based valve repair. The system for treating mitral valve regurgitation comprises a catheter, a sleeve carried within the catheter, the sleeve including a plurality of openings formed in a side wall of the sleeve and an elongate member received in the sleeve. The elongate member includes a plurality of radially extendible barbs corresponding to the sidewall openings. The sleeve carrying the elongate member is deployed adjacent a mitral valve annulus and the elongate member is translated relative to the sleeve to deploy the barbs through the sidewall openings and into the annulus and to further translate the sleeve with deployed barbs to reshape the annulus.

[00012] Another aspect of the invention provides a method for treating mitral valve regurgitation. The method comprises deploying a sleeve carrying an elongate member adjacent a mitral valve annulus via a catheter, translating the elongate member relative to the sleeve, inserting barb portions of the elongate member through sleeve sidewall openings and into the annulus responsive to the translation and translating the inserted barbs and sleeve with the elongate member to reshape the annulus.

[00013] Another aspect of the invention provides a system for treating mitral valve regurgitation. The system comprises means for reducing a mitral valve annulus, means for translating an elongate member relative to a sleeve, means for inserting barb portions of the elongate member through sleeve sidewall openings and into the annulus responsive to the translation and means for locking the elongate member relative to the sleeve.

[00014] The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention, rather than limiting the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[00015] **FIG. 1** shows a cardiac valve annulus reduction delivery system made in accordance with the present invention;

[00016] **FIG. 2** shows a cardiac valve annulus reduction delivery system made in accordance with the present invention deploying an annulus reducer;

[00017] **FIG. 3** shows a cardiac valve annulus reducer made in accordance with the present invention;

[00018] **FIG. 4** shows deployment of a cardiac valve annulus reducer made in accordance with the present invention;

[00019] **FIGS. 5-6** show detailed views of a deployed cardiac valve annulus reducer made in accordance with the present invention;

[00020] **FIGS. 7-8** show deployment of another cardiac valve annulus reducer made in accordance with the present invention;

[00021] **FIGS. 9** shows a flow chart for a method of use for a cardiac valve annulus reducer made in accordance with the present invention; and

[00022] **FIGS. 10-12** show another embodiment of a cardiac valve annulus reducer made in accordance with the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

[00023] **FIG. 1** shows a cardiac valve annulus reducer delivery system made in accordance with the present invention. The annulus reducer delivery system 100 includes a delivery catheter 110, having a central lumen

114. System 100 also includes annulus reduction assembly 120 disposed within lumen 114. Annulus reduction assembly 120 is discussed in more detail below in **FIG. 3**.

[00024] **FIG. 2** shows a cardiac valve annulus reducer delivery system made in accordance with the present invention deploying an annulus reduction device. The annulus reducer can be delivered percutaneously. Alternatively, the annulus reducer can be delivered surgically.

[00025] For the exemplary case of mitral valve remodeling shown in **FIGS. 2** and **3**, the annulus reducer 150 is implanted from the left atrium 130. An elongate element 132 having a lumen 134, such as a catheter, is first installed to provide a path for the annulus reduction delivery system from the exterior of the patient to the left atrium 130. The annulus reduction delivery system can then be advanced through the lumen 134 so that the annulus reducer 150 is located at the mitral valve annulus 136 for deployment. **FIG. 2** illustrates a transeptal approach through the vena cava: the elongate element 132 is inserted through the femoral vein into the common iliac vein, through the inferior vena cava 138 into the right atrium 140. The transeptal wall 142 between the right atrium 140 and left atrium 130 is then punctured with a guide wire or other puncturing device at the prenatal foramen ovale, and the distal end of the elongate element 132 advanced into the left atrium 130. The annulus reducer 150 can then be advanced through the lumen 134 of the elongate element 132 to the mitral valve for implantation.

[00026] Those skilled in the art will appreciate that alternative paths to gain access to the left atrium are available. For example, another possible path would be through the radial vein into the brachial vein, through the subclavian vein, through the superior vena cava into the right atrium, and then transeptally into the left atrium. Yet another possible path would be through the femoral artery into the aorta, through the aortic valve into the left ventricle, and then through the mitral valve into the left atrium. Yet another possible path would be through the left or right pulmonary vein directly into the left atrium. For

surgical approaches with an open heart, the elongate element can be a trocar or cannula inserted directly in the superior vena cava or the aortic arch. The elongate element can then follow the same path as the percutaneous procedure to reach the left atrium, transeptally or through the cardiac valves. Transeptal approaches, whether percutaneous or surgical, may require placement of a closure device at the transeptal puncture on removal of the elongate element after the procedure. Similar percutaneous or surgical approaches can be used to access the other cardiac valves, if the annular reducer is to be implanted on a cardiac valve other than the mitral valve.

[00027] Referring now to **FIGS. 3-6** where like elements have like reference numbers to those of **FIGS. 1** and **2**.

[00028] **FIG. 3** shows a cardiac valve annulus reduction assembly 120 made in accordance with the present invention. Annulus reduction assembly 120 includes inner sheath 122, annulus reducer 150, first locking system 180 and second locking system 190. Annulus reduction assembly 120 is disposed within lumen 114 of delivery catheter 110.

[00029] The annulus reducer 150 is shown in the compressed configuration as it is disposed within the lumen 114 of the delivery catheter 110 before deployment at the valve annulus. The annulus reducer 150 comprises reducer housing 160, barb assembly 170 and locking members 152. The proximal portion of the annulus reducer is disposed within lumen 124 of inner sheath 122.

[00030] Reducer housing 160 is composed of any suitable flexible biocompatible material as are well known in the art. For example the material may comprise a metallic base or a polymeric base, such as stainless steel, nitinol, tantalum, MP35N alloy, platinum, titanium, a chromium-based alloy, a cobalt-based alloy, a suitable biocompatible alloy, a suitable biocompatible material, a biocompatible polymer, or a combination thereof. Reducer housing 160 includes a first stop 162, a second stop 164 and a plurality of barb exit ports 166. Ports 166 may be any shape sized to allow the passage of barbs 174. In

one embodiment, ports 166 are oval. Ports are positioned on the reducer housing such that, when deployed, the ports are adjacent the valve annulus. Stops 162 and 164 are positioned at the proximal end of reducer housing 160. Reducer housing 160 also defines an opening 165 positioned opposite the plurality of ports 166.

[00031] Barb assembly 170 is disposed within the lumen of reducer housing 160. Barb assembly 170 includes an elongate member 172 and a plurality of barbs 174 securely attached to elongate member 172. The elongate member 172 can be made of any biocompatible material, which can be formed into a ring shape when deployed at the cardiac valve. In one embodiment, the elongate member 172 can be made of stainless steel or metal alloy like MP35n. In another embodiment, the elongate member 172 can be made of a memory metal, such as Nitinol. Each barb 174 is positioned adjacent a corresponding port 166 of the reducer housing 160. Barbs 174 may be attached to the elongate member 172 using a crimped joint, adhesive or any other method of attachment well known in the art. In one embodiment, the barbs and the elongate member are fashioned from the same piece of material. In one embodiment, barbs 174 are composed of shape memory material. Shape memory material may be, for example, nitinol, MP35N, stainless steel, ELGILOY®, super alloy or combinations thereof

[00032] Elongate member 172 also includes a gripping member 176 at the proximal end 177. In one embodiment, gripping member 176 is a spherically shaped member that corresponds with the shape of the first locking grip 188, below. Gripping member 176 is releasably held by the first locking grip 188.

[00033] Locking members 152 are attached to the distal end 178 of elongate member 172. Locking members 152 comprise a plurality of spherically shaped members disposed on a locking member support 154 in a spaced apart manner. In one embodiment, the most distal locking member 153 is a gripping member that is releasably held by a second locking grip 198. In one

embodiment, locking member support 154 is a wire securely attached to distal end of elongate member 172. In another embodiment, locking member support 154 is a tapered distal end of elongated member 172.

[00034] First locking system 180 releasably holds and manipulates elongate member 172. First locking system 180 includes a tubular body 182 having a lumen, a control wire 186 disposed within lumen 184 and a first locking grip 188. A distal end of control wire 186 is attached to the first locking grip 188 and the proximal end of the control wire 186 is operably attached to a control mechanism (not shown) operable to hold and release gripping member 176.

[00035] Second locking system 190 releasably holds and manipulates locking members 152 secured to the distal end of elongate member 172. Second locking system 190 includes a tubular body 192 having a lumen, a control wire 196 disposed within lumen 194 and a second locking grip 198. Tubular body 192 passes through opening 165 of reducer housing 160. Opening 165 is sized to allow passage of the tubular body 192 and locking members 152 through the opening and into the lumen of the reducer housing 160 during deployment. A distal end of control wire 196 is attached to the second locking grip 198 and the proximal end of the control wire 196 is operably attached to a control mechanism (not shown) operable to hold and release gripping member 153. In one embodiment, the second locking grip is shaped to correspond to the spherical shape of gripping member 153. Those with skill in the art will recognize that there are a myriad of combinations of gripping members and locking grips suitable for releasably holding and manipulating both ends of elongate member 172.

[00036] **FIG. 4** illustrates a partially deployed annulus reducer 150. After the annulus reduction assembly has been advanced through the lumen 114 of the delivery catheter 110 and positioned adjacent the annulus of the cardiac valve, the outer sheath of the delivery catheter is retracted thereby deploying the annulus reduction assembly.

[00037] The annulus reducer is formed into a general ring shape before attachment to the annulus. To form the ring shape of the annulus reducer, the user holds the proximal end of elongate member 172 in place using the locking grip 188 of the first locking system 180 thereby preventing the advancement of the elongated member. Simultaneously, the user pulls the locking members in a proximal direction (to the left in **FIG. 4**) by pulling the second locking system, which is attached to the locking members, in a proximal direction. As the user pulls the second locking system in the proximal direction, the elongate member 192 moves through opening 165 of reducer housing 160. Continued pulling results in the formation of the ring depicted in **FIG. 5**. Stop 162 prevents the advancement of elongate member 172 and allows the formation of the generally ring shaped annulus reducer.

[00038] As the elongate member 172 is pulled, each of the barbs 174 extend through a corresponding port 166 of reducer housing 160. Upon the deployment of the barb through the port, the barbs curl and contact the leading edge of their respective port resulting in the movement of both the elongate member 172 and the reducer housing as one unit as illustrated in **FIG. 6**. As the barbs are deployed, the barbs enter the valve annulus. Full deployment of the barbs anchors the annular reducer to the valve annulus.

[00039] As the user continues to pull on the anchored annular reducer, the distal end of the reducer housing moves closer to the opening 165 of the reducer housing thereby drawing together the two ends of the annulus reducer.. Consequently, the valve annulus is remodeled resulting in the bringing together of the valve leaflets. This results in the reduction or elimination of valve regurgitation.

[00040] The annulus reduction device is locked in place using a ratchet style locking system. In one embodiment, the annulus reduction device is locked in place using the locking members 152 and the second stop 164. As the locking system 190 is pulled through opening 165 at least one locking member passes stop 164. Stop 164 allows the movement of locking members 152 in one

direction but prevents the locking member from moving in the opposite direction. Referring to **FIG. 4**, as an example, stop 164 allows the passage of locking member from right to left but does not allow the movement of the locking member in the opposite direction (left to right) once the locking member has passed the stop. Stop 164 may be a spring biased to prevent the movement of the passed locking member.

[00041] The annulus reduction device 150 is released from locking systems 180 and 190 after the annulus reduction device is locked into place using locking members 152 and stop 164. To release the device from the locking grips 188 and 198, the user manipulates the respective control wires 186 and 196 to open the grips. Once released, the delivery catheter, inner sheath and locking systems may be retracted and removed from the patient's body.

[00042] **FIGS. 7** and **8** illustrate another embodiment of the annulus reducer 700 deployed at the annulus 710 of a mitral valve 720. **FIG. 7** shows the deployment of the plurality of barbs 730 just as they are poised to enter the annulus to anchor the device to the annulus. **FIG. 8** shows the resulting ability of the valve leaflets 740 to open and close more normally as the distal end 750 of the anchored device is pulled closer to the proximal 760 end of the device.

[00043] Those with skill in the art will recognize that there are other embodiments contemplated by the present invention. In another embodiment, the annulus reducer is placed within the delivery catheter in a compressed or folded loop formation such that as the outer sheath of the delivery catheter is retracted the reducer expands to form the loop. In this embodiment the elongate member may be formed of a shape memory material that when released from the delivery catheter retakes the expanded shape.

[00044] **FIG. 9** shows a flow chart for a method of use for a cardiac valve annulus reducer made in accordance with the present invention. An exemplary embodiment provides a method 400 for treating mitral valve regurgitation. The method begins by delivering an annulus reduction device 150 adjacent to the mitral valve annulus (Block 410) using, for example, a delivery

catheter. The annulus reduction device can be delivered percutaneously or surgically. Once delivered, the delivery catheter sheath may be retracted to deploy the annulus reduction device (Block 420). In another embodiment, the annulus reduction device can be advanced through the delivery catheter in order to deploy the device.

[00045] The annulus reduction device includes a sleeve portion 160 with a plurality of ports 166, and an elongate portion (wire) 172 having a plurality of barbs 174 attached thereto. The elongate portion 172 has a proximal end with a gripping member 176 and a distal end 178 having a locking member 152 attached. The gripping member 176 and the locking member are each held by a releasable locking system 180 and 190, respectively. Locking systems 180 and 190 are used to translate the annulus reduction device and to form the looped structure after the device is deployed.

[00046] Upon deployment, the user forms the looped structure of the annulus reduction device (Block 430). In one embodiment, the loop is formed by holding the gripping member 176 in place while translating (pulling) on the locking member attached to the distal end of the elongate member. The locking member is translated using the locking system 190 releasably attached to the distal end 153 of the locking member. This action results in the looped structure depicted in **FIG. 5**.

[00047] Continued translation of the elongate member 172 releases the barbs through the ports of the sleeve sidewall and into the annulus adjacent the ports (Block 440). Upon release and further translation, the proximal portion of each barb abuts the respective port resulting in the movement of the elongate member and the sleeve as one unit. In addition, upon release, the barbs enter the valve annulus to securely grip the annulus.

[00048] The annulus reduction device is further translated to reshape the annulus (Block 450). The annulus is reshaped by pulling the leaflets of the mitral valve together and locking the annulus reduction device in place.

[00049] The annulus reduction device is locked in place by the engagement of the locking members with the stop 164 (Block 460). As the locking members pass the stop, the members are prevented from backward movement. This engagement locks the annulus reduction device in the ring formation.

[00050] **FIGS. 10-12** show another embodiment of a cardiac valve annulus reducer system 1000 made in accordance with the present invention.

[00051] FIG. 10 shows a detailed view of the annulus reducer assembly 1015 disposed within the distal portion of a lumen of a delivery catheter 1010. Annulus reducer assembly 1015 includes reducer housing 1020, elongate member 1030, locking assembly 1050 and a holding cord 1060.

[00052] Reducer housing 1020 includes a plurality of ports 1025 and a central lumen 1022. Elongate member 1030 is disposed within lumen 1022 of reducer housing 1020. Elongate member 1030 includes a plurality of barbs 1035 positioned adjacent ports 1025. Barbs 1035 may be composed of such materials as nitinol, MP35N, stainless steel, ELGILOY®, super alloy or combinations thereof. Elongate member also includes a proximal end 1032 and a distal end 1034. Proximal end 1032 is secured to lock 1070, as best seen in **FIG. 11**.

[00053] Locking assembly 1050 is attached to the distal end 1034 of elongate member 1030. Locking assembly 1050 includes a plurality of locking members (keys) 1052 disposed upon a locking member support 1054. Each locking member also includes a stop member 1056. Stop members 1056 are axially aligned with the elongate member 1030 before deployment of the annulus reducer, see FIG 10. Upon deployment, the stop members 1056 extend radially, as best seen in FIG 11.

[00054] Holding cord 1060 is attached to the distal end of locking assembly 1050. Holding cord 1060 is disposed within a lumen of lock 1070 and extends to a control mechanism (not shown) for manipulation by the physician.

[00055] Annulus reduction assembly further includes a holding tube 1080. Holding tube 1080 is positioned proximal to lock 1070. Holding tube 1080

includes a lumen through which the holding cord 1060 passes. In one embodiment, holding tube 1080 holds lock 1070 in place, keeping it from moving in a proximal direction as the annulus reduction ring is formed.

[00056] In operation, the annulus reducer assembly is delivered to the cardiac valve annulus in a manner as discussed above in FIG. 2. Once at the target valve, the annulus reducer assembly is deployed adjacent or within the valve annulus. The physician then forms the general ring structure of the annulus reducer by pulling the holding cord 1060 in a proximal direction while at the same time keeping the proximal end 1032 of the elongate member 1030 stationary. The movement of the holding cord 1060 translates the elongate member 1030 so that the barbs 1035 that are constrained within the lumen of the elongate member 1030 extend through a corresponding port 1025 of the reducer housing 1020 and penetrate the annulus of the target valve.

[00057] Continued translation of the elongate member 1030 results in the remodeling (reduction) of the valve annulus. The remodeling of the valve annulus improves the valve's ability to open and close more normally.

[00058] Once the valve annulus is remodeled to the desired size and shape the valve annulus reducer assembly 1015 is locked into position. The annulus reducer assembly 1015 is locked by further translation of the locking assembly 1050 towards lock 1070. The locking mechanism is actuated by the movement of at least one of the locking members 1052 through the lumen of lock 1070 to pass through the lock. As the lock passes through the lock, stop 1056 assumes an axial position similar to that when it was constrained within the delivery lumen. Once the stop passes through to the opposite side of the lock the stop 1056 extends in a radial direction.

[00059] The annulus reduction assembly 1015 is locked in place using a ratchet style locking system. In one embodiment, the annulus reduction assembly 1015 is locked in place using the locking members 1052 and lock 1070. As the locking system 1050 is pulled through the lumen of lock 1070 at least one locking member 1052 passes lock 1070. Stop 1056 allows the

movement of locking members 1052 in one direction but prevents the locking member from moving in the opposite direction.

[00060] It is important to note that **FIGS. 1-12** illustrate specific applications and embodiments of the present invention, and is not intended to limit the scope of the present disclosure or claims to that which is presented therein. Upon reading the specification and reviewing the drawings hereof, it will become immediately obvious to those skilled in the art that myriad other embodiments of the present invention are possible, and that such embodiments are contemplated and fall within the scope of the presently claimed invention.

[00061] While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.

CLAIMS

1. A system for treating mitral valve regurgitation, the system comprising:

a catheter;

a sleeve carried within the catheter, the sleeve including a plurality of openings formed in a side wall of the sleeve;

an elongate member received in the sleeve, the elongate member including a plurality of radially extendible barbs corresponding to the sidewall openings, wherein the sleeve carrying the elongate member is deployed adjacent a mitral valve annulus and the elongate member is translated relative to the sleeve to deploy the barbs through the sidewall openings and into the annulus and to further translate the sleeve with the deployed barbs to reshape the annulus.

2. The system of claim 1 further comprising:

a locking mechanism to maintain the deployed sleeve with deployed barbs in a desired position.

3. The system of claim 2 wherein the locking mechanism comprises a plurality of locking members securely attached to a locking member support, the locking member support attached to a distal end of the elongate member and a stop member attached to a proximal portion of the sleeve, the stop member for locking engagement with at least one of the plurality of locking members.

4. The system of claim 1 further comprising:

a first locking system releasably attached to a proximal end of the elongate member.

5. The system of claim 2 further comprising:

a second locking system releasably attached to a distal end of the locking mechanism.

6. The system of claim 4 wherein the first locking system comprises a first tubular body having a lumen, a first control wire disposed in the lumen and attached to a first locking grip disposed at a distal end of the first tubular body, the first locking grip for locking engagement with a proximal portion of the elongate member.

7. The system of claim 5 wherein the second locking system comprises a second tubular body having a lumen, a second control wire disposed in the lumen and attached to a second locking grip disposed at a distal end of the second tubular body, the second locking grip for locking engagement with the locking mechanism.

8. The system of claim 1 wherein the elongate member comprises a wire.

9. The system of claim 1 wherein the barbs are composed of a shape memory material.

10. The system of claim 9 wherein the shape memory is a material chosen from a group consisting of nitinol, MP35N, stainless steel, ELGILOY®, super alloy or combinations thereof.

11. A method for treating mitral valve regurgitation, the method comprising:

deploying a sleeve carrying an elongate member adjacent a mitral valve annulus via a catheter;

translating the elongate member relative to the sleeve;

inserting barb portions of the elongate member through sleeve sidewall openings and into the annulus responsive to the translation; and

translating the inserted barbs and sleeve with the elongate member to reshape the annulus.

12. The method of claim 11 wherein translating the elongate member relative to the sleeve comprises gripping a locking member securely attached to a distal end of the elongate member and pulling the elongate member in a proximal direction to form a loop.

13. The method of claim 12 further comprising:

locking the elongate member in the loop formation by engaging the locking member with a stop located on a proximal end of the sleeve.

14. A system for treating mitral valve regurgitation, the system comprising:

means for reducing a mitral valve annulus;

means for translating an elongate member relative to a sleeve;

means for inserting barb portions of the elongate member through sleeve sidewall openings and into the annulus responsive to the translation; and

means for locking the elongate member relative to the sleeve.

ABSTRACT OF THE DISCLOSURE

The cardiac valve annulus reducer system of the present invention, and method of using the same provides a cardiac valve annulus reduction system to provide catheter based valve repair. The system for treating mitral valve regurgitation comprises a catheter, a sleeve carried within the catheter, the sleeve including a plurality of openings formed in a side wall of the sleeve and an elongate member received in the sleeve. The elongate member includes a plurality of radially extendible barbs corresponding to the sidewall openings. The sleeve carrying the elongate member is deployed adjacent a mitral valve annulus and the elongate member is translated relative to the sleeve to deploy the barbs through the sidewall openings and into the annulus and to further translate the sleeve with deployed barbs to reshape the annulus.

FIG. 1

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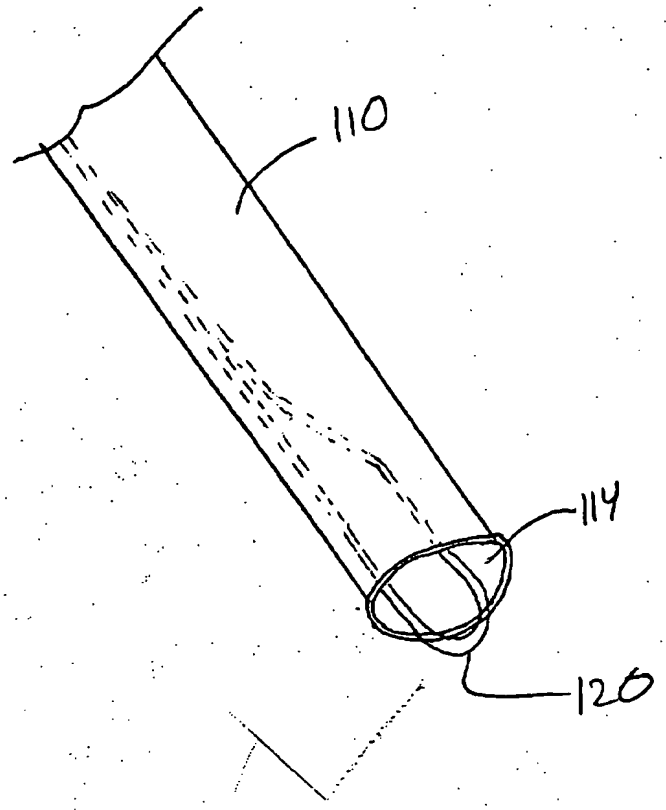

Fig. 2

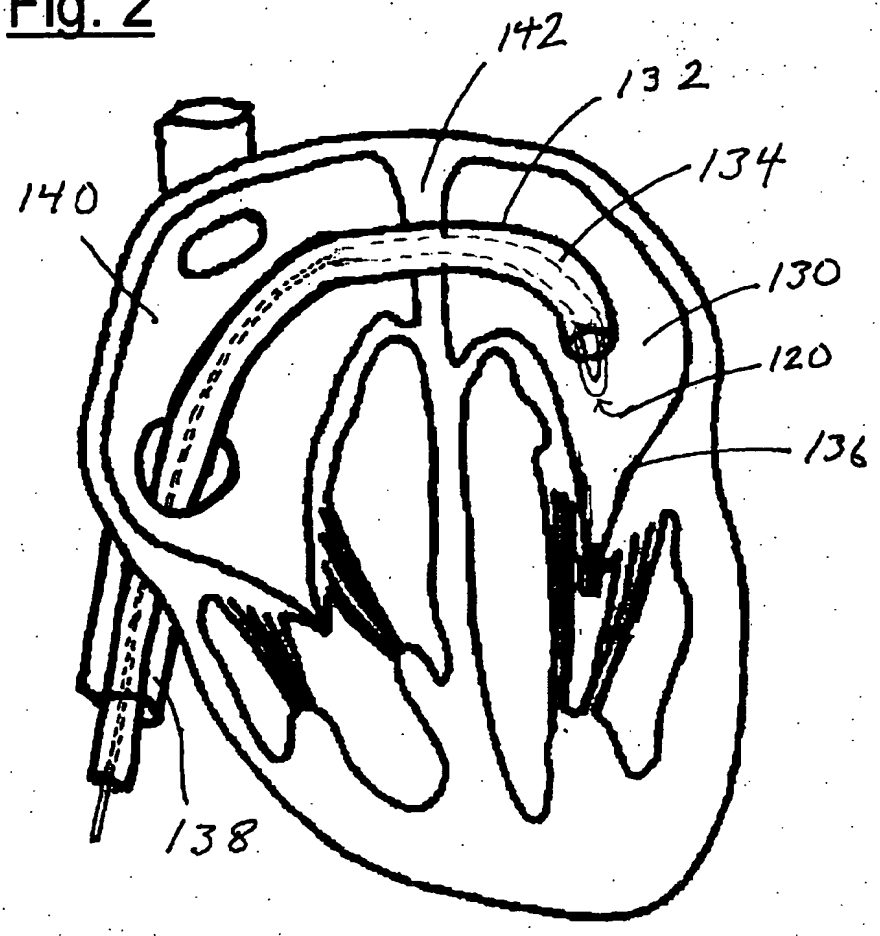

FIG. 3

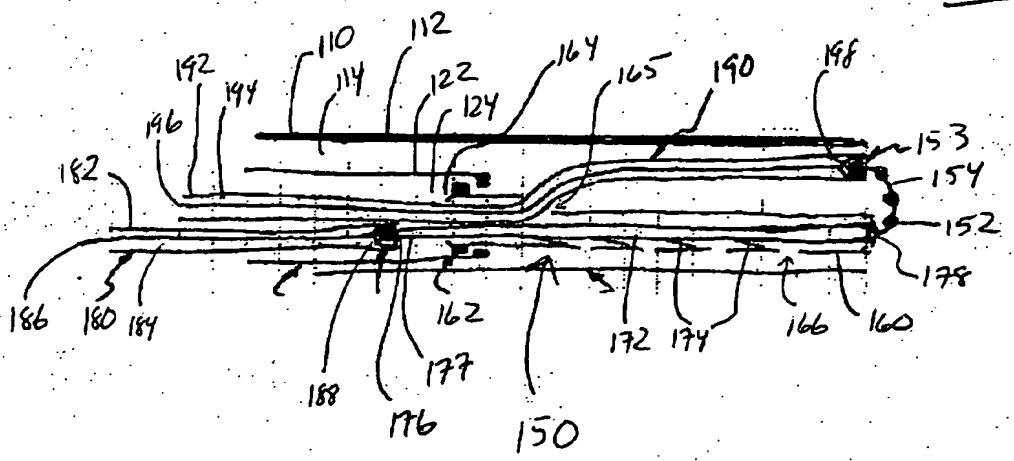
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FIG. 4

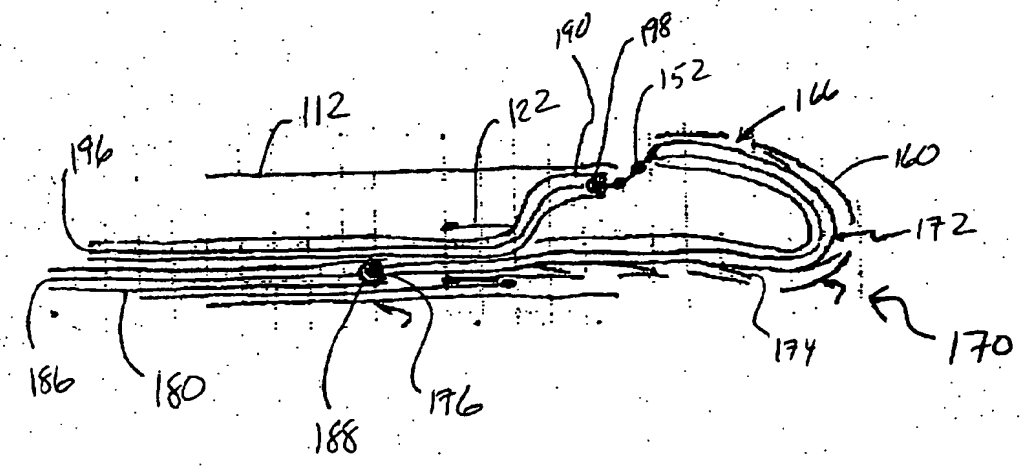
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FIG. 5

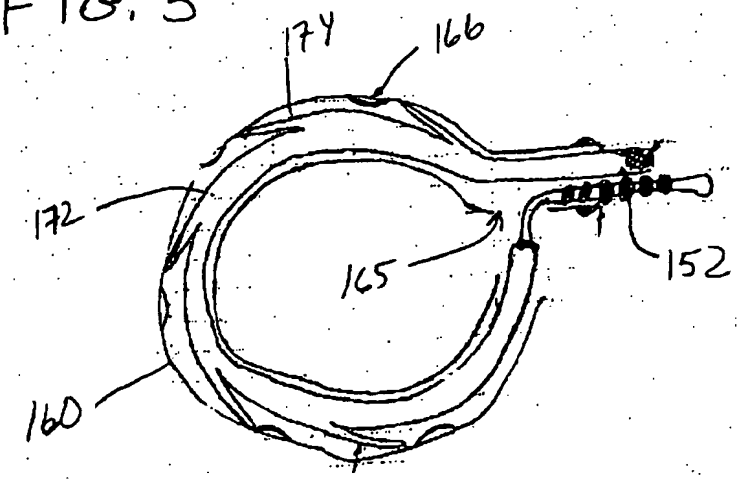
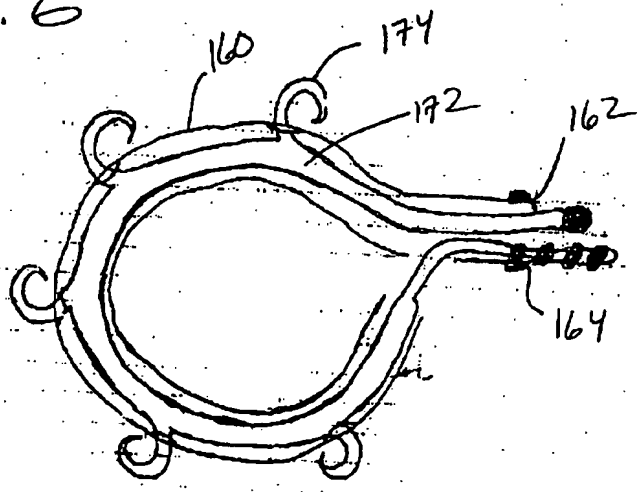


FIG. 6



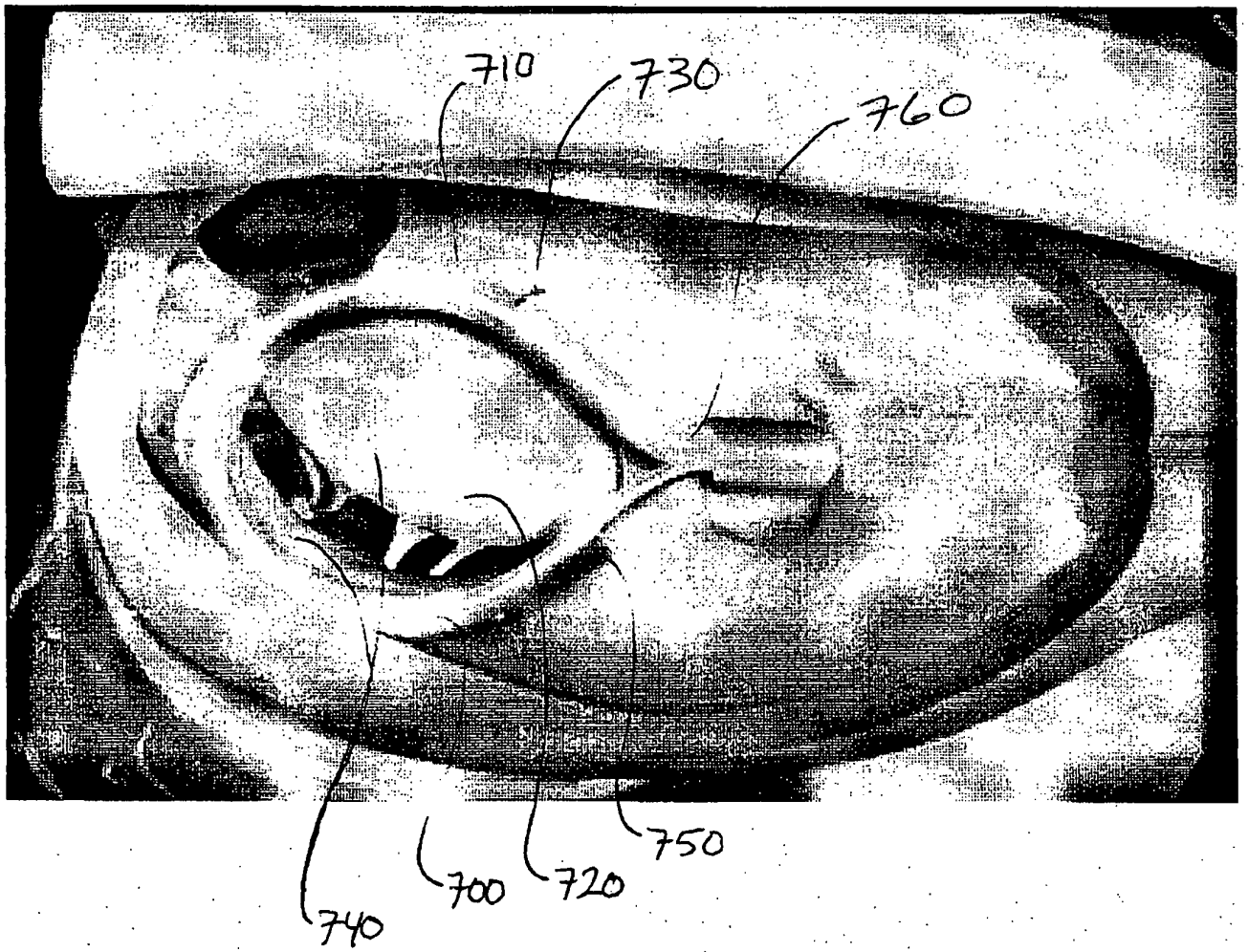


FIG. 7

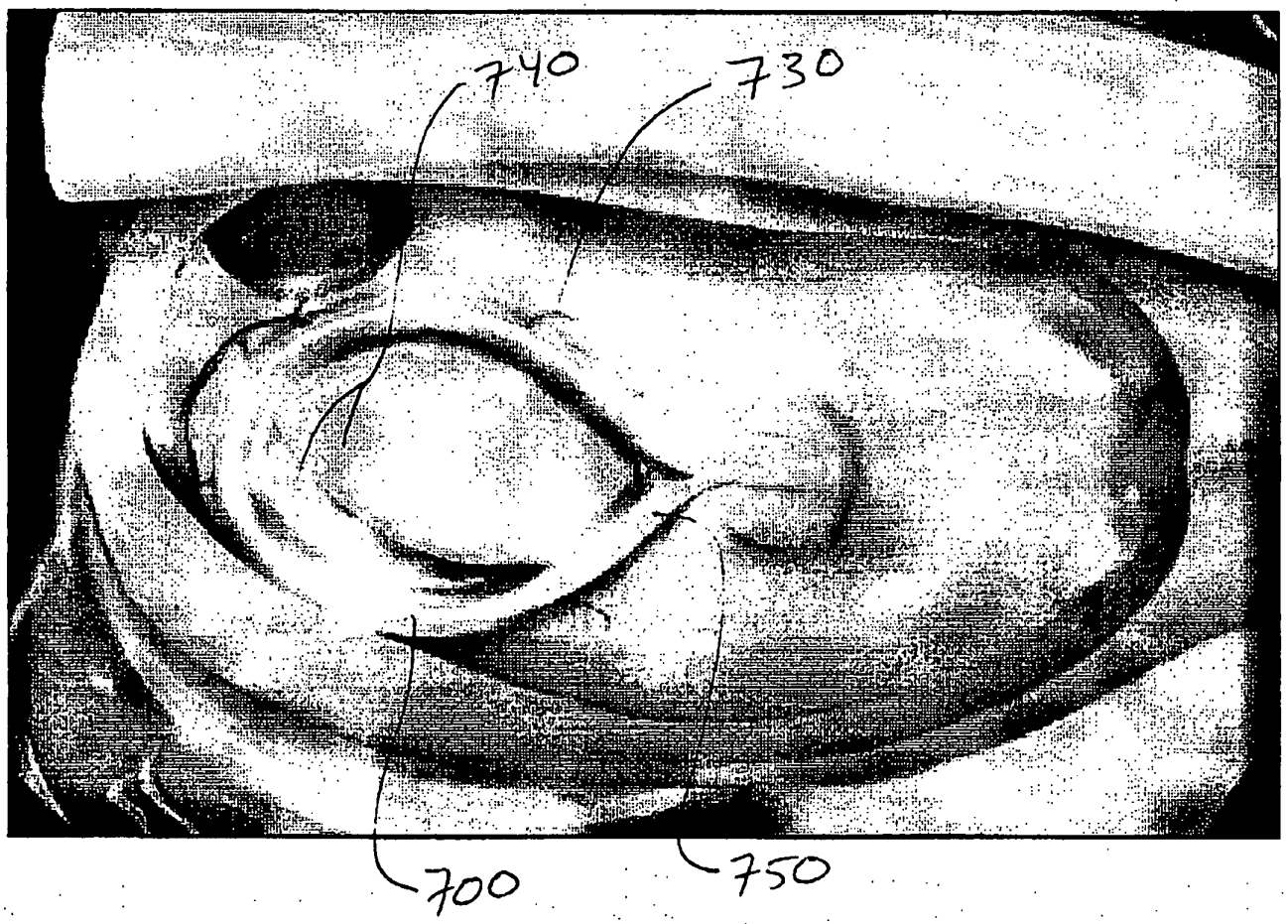
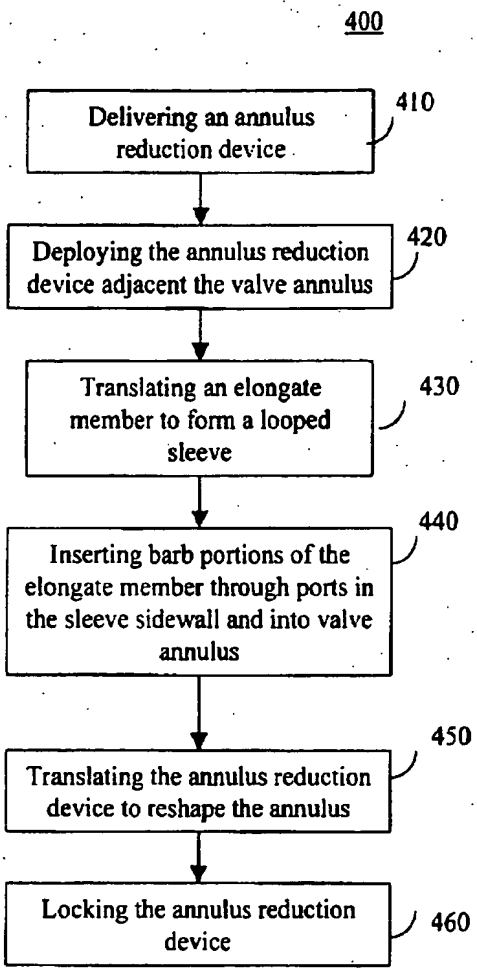


FIG. 8

FIG. 9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Delivering an annulus reduction device
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Deploying the annulus reduction device adjacent the valve annulus
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Translating an elongate member to form a looped sleeve
430
Inserting barb portions of the elongate member through ports in the sleeve sidewall and into valve annulus
440
Translating the annulus reduction device to reshape the annulus
450
Locking the annulus reduction device
460

FIG. 10

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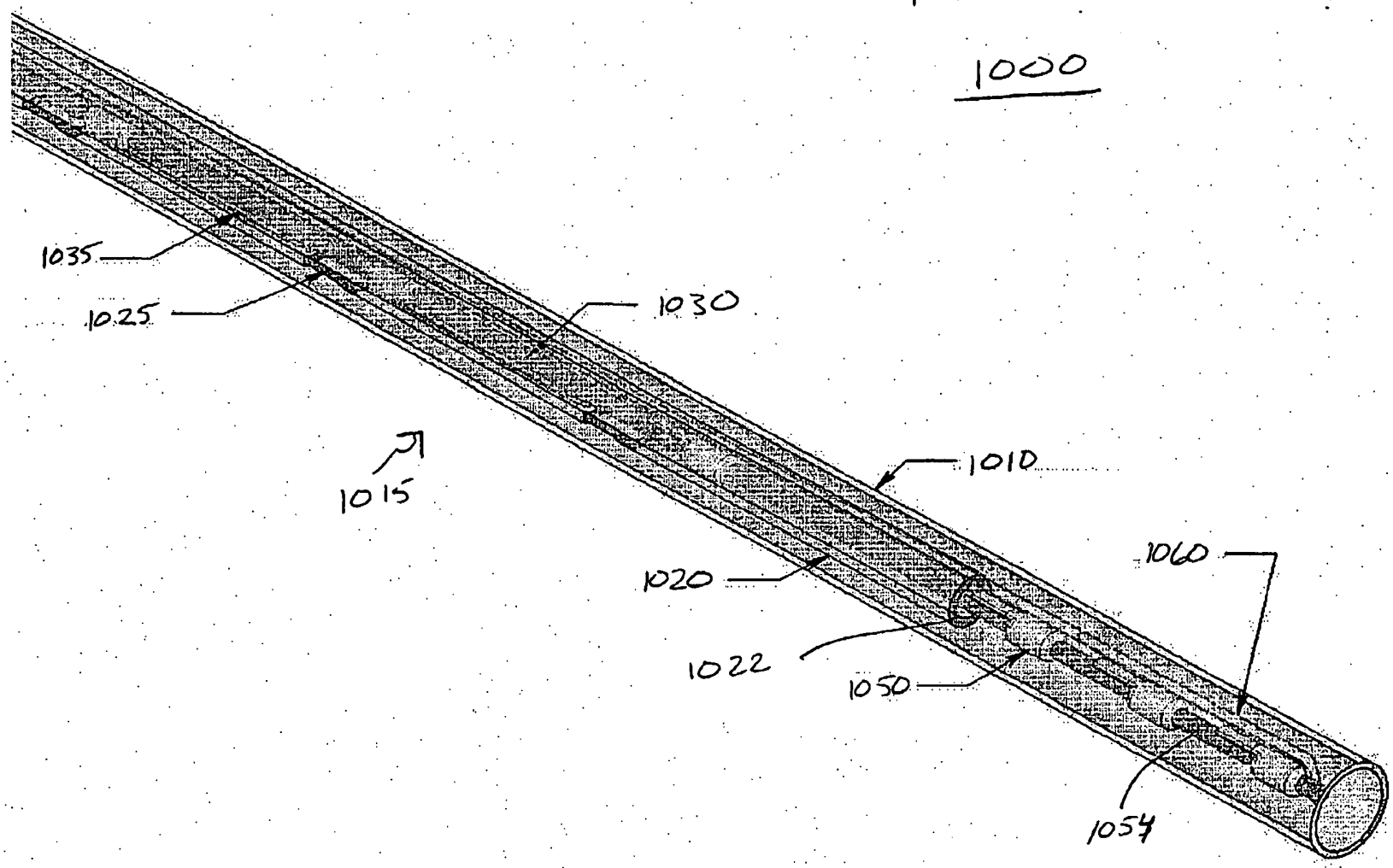

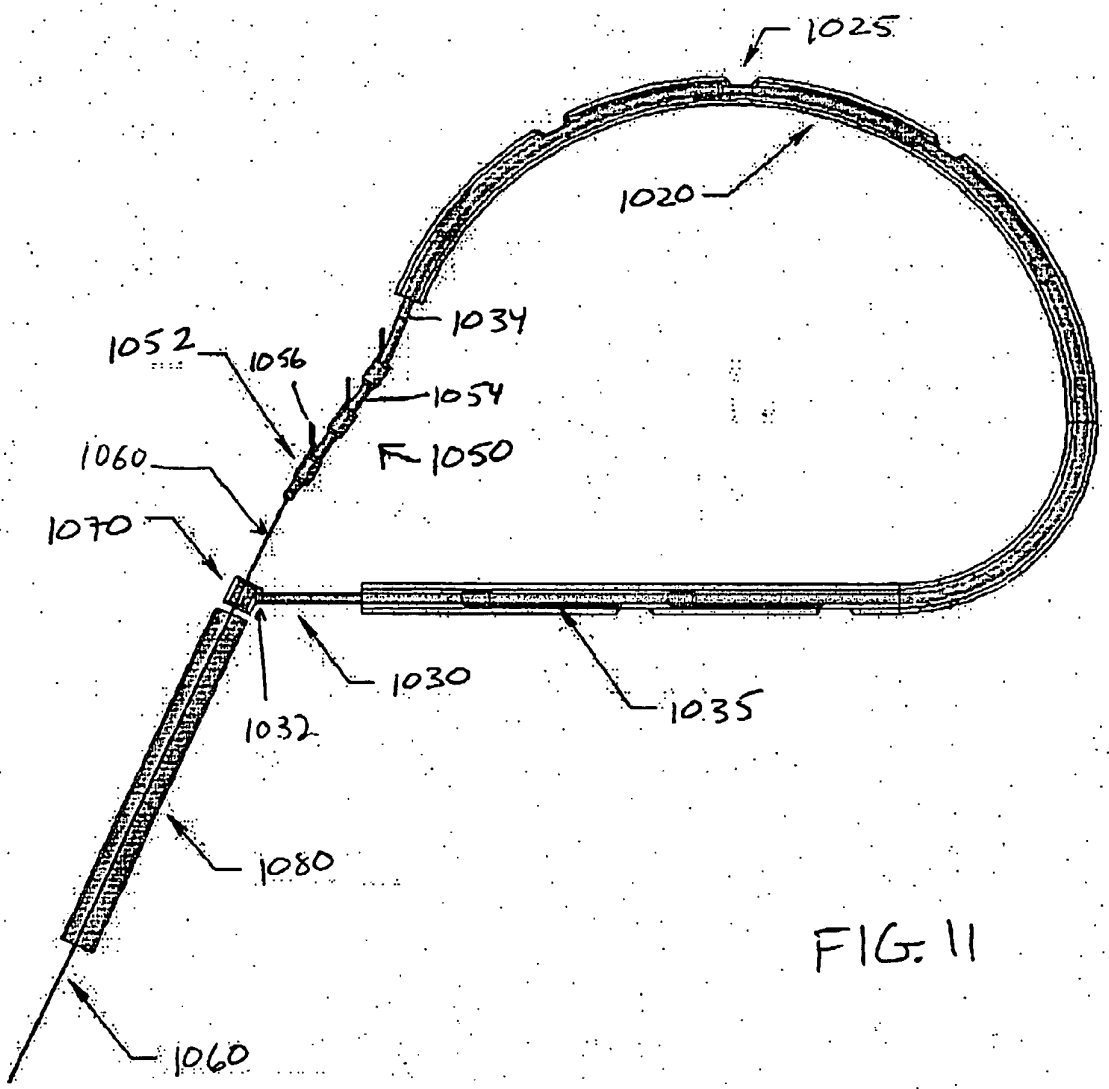
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FIG. 11

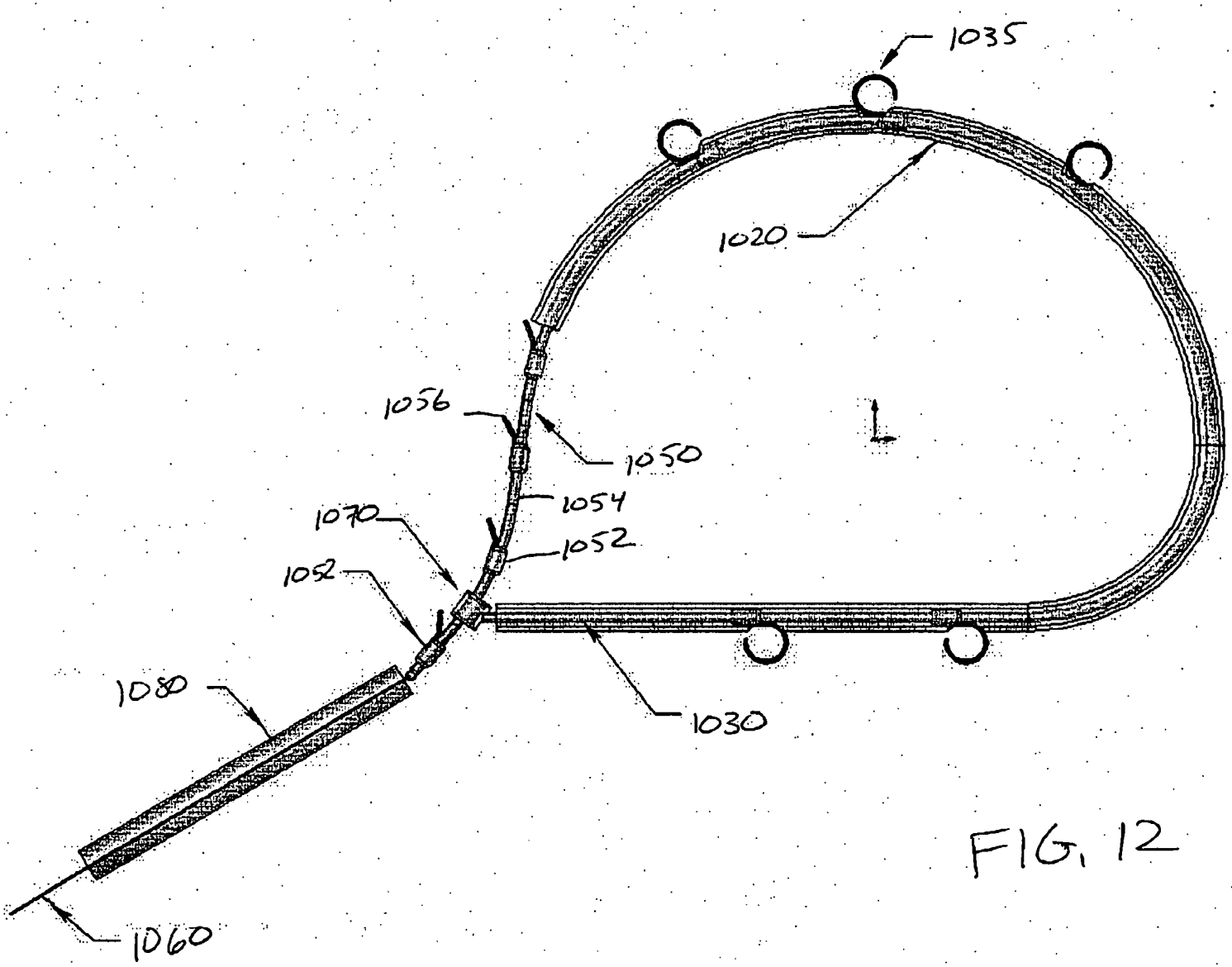

FIG. 12